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09/347,311	07/02/1999	GEERT PLAETINCK	B0192/7010	3674

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JOHN R VAN AMSTERDAM
C/O WOLF GREENFIELD & SACKS P C
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 022102211

EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

25

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/347,311

Applicant(s)

PLAETINCK ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 and 49-92 is/are pending in the application.
- 4a) Of the above claim(s) 16,22,25-37,46 and 49-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-21, 23, 24, 38-45, ~~48~~, 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to. 7W 41110
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

This application, filed July 2, 1999, claims benefit of foreign applications: GB 9814536.0, filed July 3, 1998, and GB 9827152.1, filed December 9, 1998, both filed in Great Britain.

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). As noted previously, Applicants' after final amendment filed May 14, 2002, paper number 22, had been entered. Claim 48 was been canceled. Claims 1, 12, 14, 20, 38 and 92 were amended.

Claims 1-47 and 49-92 are pending. Claims 16, 22, 25-37, 46 and 49-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 17. Claims 1-15, 17-21, 23, 24, 38-45, 47, 48 and 92 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed September 12, 2002 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. A copy of the signed PTO-1449 has been included with this action.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 17-21, 23, 24, 38-45, 47, 48 and 92 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn.

The amendments to the claims to encompass subject matter considered to be enabled has obviated the basis of the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15, 17-21, 23, 24, 38-45, 47, 48 and 92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically;

The claims have been amended to recite “a *C. elegans* cell or organism” (see claim 1, step (a) for example) however it is unclear if the claims encompass any organism or if the amendment was made to encompass a *C. elegans* worm and a cell from a *C. elegans*. More clearly indicating if *C. elegans* is related to both the cell and the organism, or if the claims encompass practice in any organism would obviate the basis of this rejection.

Claim 1 recites the limitation "cDNA fragment" in step c). There is insufficient antecedent basis for this limitation in the claim. The claim indicates that a cDNA library is made, however there is no recitation or indication that the cDNA library constitutes fragments.

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The claim is unclear because what is identified in step c) is not clearly set forth relative to what is administered. It is unclear if the claim simply identifies the DNA inserted into the vector, or an additional step wherein the inserted DNA is further characterized to define the specific sequences responsible for conferring the phenotype.

Claim 12 is unclear as to whether it represents a second element of if may simply encompass the sequences encoding the dsRNA altering the phenotype. The specification does not appear to support any selectable marker that inhibits or prevents expression of a gene conferring a phenotype in *C. elegans* except for the generating dsRNA, however this was not taught to be in general a selectable marker present on a vector.

Claim 14 is unclear to what elements are required to practice the method step as claimed. The claim sets forth sequences for homologous recombination and inhibiting expression, however it is unclear how these sequences are related and how the integration of homologous sequence would result in decreased expression if it is the same homologous sequence being inserted. More clearly setting forth the elements of the vector, or how the method step is specifically practiced would obviate the basis of the rejection.

Claim 20 is unclear in the recitation and use of a "specified compound". First, it is unclear how "specified" is meant to modify the "compound" contacted to the cell or organism, and how this would distinguish it from any compound. Second, it is unclear how this is related to a specific "desired phenotype" or what makes a particular phenotype desirable. "Desired" is a subjective term and would be variable from one artisan to another. Finally, the claim is unclear as how it is related to the methods set forth in claims 1 and 3. Claim 20 simply sets forth a method step without indicating where or when would practice it in the context of the methods of

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claims 1 and 3. More clearly setting forth claim 20 as a separate method or indicating more clearly how the method step is related to claims 1 and 3 would obviate the basis of the rejection.

Claim 92 is vague and confusing because it appears to be a circular definition attempting to define a specified compound as it is related to a desired phenotype. The claim is unclear because one can not define one variable with another, in particular since it has to be compared and apparently is not normally present in wild type *C. elegans*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15, 17-21, 23, 24, 38-45, 47, 48 and 92 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire *et al.* (US Patent 6,506,559 B1).

Fire *et al.* teach that dsRNA can be used in *C. elegans* to inhibit the expression of endogenous gene. The dsRNA can be administered to *C. elegans* in a variety of ways, including through the ingestion of a bacteria that expresses and provides for dsRNA (column 5, lines 9-11). Fire *et al.* provide a variety of methods in which this system can be used to inhibit gene expression in *C. elegans* including determining the importance of any genes expression (column 5, lines 34-37). In detail Fire *et al.* provide methods for making DNA libraries in vectors, where the resulting vectors are capable of generating dsRNA from the inserted DNA (starting in

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column 12, line 16). Fire *et al.* teach that the vectors that express dsRNA can be used to determine any genes function in a high throughput manner. Thus, the methods and materials taught by Fire *et al.* anticipate the instantly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15, 17-21, 23, 24, 38-45, 47, 48 and 92 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 10/057,108. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods are both drawn to administering dsRNA to *C. elegans* through the use of a micro-organism. Each require the use of vectors that express a DNA and result in a dsRNA. Each encompass the use of a DNA library and for providing the micro-organism comprising the vector to *C. elegans* in order to determine the phenotypic affect of silencing the expression of a gene.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

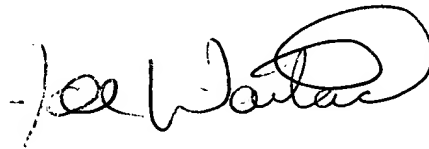
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



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